U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street, 3rd floor
New York, New York 10007

June 19, 2015

BY ECF

Hon. Paul G. Gardephe
United States District Judge
United States Courthouse
40 Foley Square
New York, NY 10007

Re: *United States v. Novartis*, No. 11 Civ. 0071 (PGG)

Dear Judge Gardephe:

The United States of America (the "United States" or "Government") writes in accordance with Paragraph 4.A of this Court's Individual Rules of Practice to respectfully request a pre-motion conference with respect to the Government's anticipated motion to compel defendant Novartis Pharmaceuticals Corporation ("Novartis") to produce certain information regarding (1) promotional speaker program events relating to the ten Novartis drugs at issue in this case, and (2) prescriptions written for the ten drugs, all for the time period running from January 1, 2001 through December 31, 2014. A status conference is currently scheduled in this case for June 23, 2015, and the Government respectfully requests that this matter be heard at that time.

Allegations in the Amended Complaint

The United States has brought claims for violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729(a)(1)(A)-(B), and unjust enrichment. The Government alleges that, from January 2002 through at least November 2011, Novartis paid doctors through its so-called speaker program events to induce doctors to increase their prescriptions of ten Novartis drugs, causing false claims for reimbursement to be submitted to federal healthcare programs. The ten drugs at issue are Lotrel, Valturna, Starlix, Diovan, Diovan HTC, Tekturna, Tekturna HTC, Exforge, Exforge HTC, and Tekamlo (the "Covered Drugs"). Of these, three drugs—Diovan, Exforge, and Tekturna (the "Released Drugs")—were the subject of a settlement between the Government and Novartis, dated September 29, 2010 (the "2010 Release"), which released Novartis from past and future claims for speaker programs promoting the Released Drugs from January 1, 2002 to December 31, 2009 (the "Released Period"). A copy of the 2010 Release is attached as Exhibit A.

The Government's Discovery Requests

At issue are two of the Government's requests for production of documents. First, the Government has requested the nationwide speaker program data maintained by Novartis in its payment and expense reporting system relating to the ten drugs at issue (the "Speaker Program Data"). The Speaker Program Data sets forth information regarding every Novartis speaker program event held for the ten drugs, including dates, locations and topics of events, names of doctors involved, amounts spent on events, and amounts of honoraria paid. Second, the Government has requested prescription-writing data acquired by Novartis relating to the ten drugs at issue (the "Prescription Data"). The Prescription Data sets forth information regarding prescriptions written for the ten drugs, including prescribing doctors' names, drugs prescribed, and dates of prescriptions. The Government has requested Speaker Program Data and Prescription Data for the time period running from January 1, 2001 through December 31, 2014, to the extent that information is available.[1]

Novartis's Refusal to Produce the Requested Information

Novartis has produced only a subset of the requested Speaker Program Data and Prescription Data. Specifically, for Lotrel, Valturna, and Starlix, Novartis has produced data for the time period running from January 1, 2002, through November 31, 2011. For the remaining seven drugs at issue, Novartis has produced Speaker Program Data and Prescription Data for the time period January 1, 2010, through November 31, 2011.

Novartis has refused to provide data for the other time periods, arguing that the information is irrelevant. As to the requested 2002-2009 data relating to the three Released Drugs, Novartis has argued that data from the Released Period cannot be relevant because the Government has released claims for those drugs during that time period. Novartis has also refused to produce the requested pre-2010 data for Diovan HCT, Tekturna HCT, and Exforge HCT, asserting that these drugs are also covered by the 2010 Release. Finally, Novartis has argued that pre-2002 and post-2011 data for any of the Covered Drugs cannot be relevant to this case because the Amended Complaint does not allege any specific violations of the FCA during those time periods.

[1] The data sought will necessarily be limited by the timing of each drug's entry into (and exit from) the U.S. pharmaceutical drug market. The Government understands that, of the ten Covered Drugs, only Lotrel, Diovan, Diovan HCT, and Starlix were on the market in 2001. The remaining six drugs were not approved by the FDA until 2007 at the earliest. In addition, Novartis has represented that it is not in possession of any Prescription Data for 2001. Accordingly, with respect to the pre-2002 time period, the Government is only seeking Speaker Program Data for four of the Novartis drugs at issue in this case. With regard to the post-2011 time period, the Government understands Valturna was discontinued in 2012 and that there is thus no Speaker Program Data or Prescription Data for Valturna for 2013 or 2014.

The parties have met and conferred on these issues on three separate occasions, but have been unable to resolve this discovery dispute.

The Requested Information is Relevant to the Government's Claims

The Speaker Program Data and the Prescription Data requested by the Government is relevant to the Government's claims in this case. As an initial matter, contrary to the position taken by Novartis, much of the requested information relates directly to time periods and claims that are included within the ambit of the Complaint. With respect to the post-2011 time period, the Complaint alleges a continuing pattern or practice of violations that continued through "at least November 2011," Am. Compl. ¶ 1, and does not limit its claims to the pre-2011 time period. For that reason alone, the post-2011 Speaker Program Data and Prescription Data is discoverable.

The Government has also expressly asserted claims relating to sham speaker programs held for Diovan HCT, Exforge HCT, and Tekturna HCT during the Released Period. Am. Compl. ¶¶ 172-173. Speaker Program Data and Prescription Data for these HCT drugs during the Released Period is plainly relevant to these claims. The central premise underlying the Amended Complaint is that Novartis used its speaker program events to provide remuneration to health care providers to induce such doctors to prescribe Novartis drugs. Information regarding doctors' attendance at particular speaker program events and their prescriptions of Novartis drugs goes to the heart of the Government's claims.

Novartis has nonetheless refused to provide Speaker Program Data and Prescription Data for the HCT drugs for the Released Period, arguing that the Government is prohibited from pursuing claims arising from speaker programs conducted during the Released Period for the HCT drugs by the terms of the 2010 Release. The premise of this objection is demonstrably false. The 2010 Release only releases claims relating to Diovan, Exforge, and Tekturna, not the HCT versions of these drugs. Presumably for this reason, Novartis did not move to dismiss the Government's claims relating to the HCT drugs on the grounds that these claims were the subject of the 2010 Release, and those claims are still pending in this action. The Government is therefore entitled to discovery on these live claims.

Even leaving these discrete issues aside, Speaker Program Data and Prescription Data for all of the Covered Drugs for the entire time period from 2001 through 2014 is relevant to this case and should be produced to the Government. Contrary to Novartis's position, the time period of allegations in a complaint does not define the time period of relevant discovery. Rather, under Rule 26(b)(1), "[p]arties may obtain discovery regarding any non-privileged matter that is relevant to any party's claim or defense." The term "relevance" under Rule 26 "has been construed broadly to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on any issue that is or may be in the case." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351,

(1978). "Thus, as a general matter, all potentially relevant material is discoverable." *Xpedior Creditor Trust v. Credit Suisse First Boston (USA), Inc.*, 309 F. Supp. 2d 459, 461 (S.D.N.Y. 2003). Accordingly, courts routinely permit discovery of periods before and after events alleged in a complaint, so long as the information sought is potentially relevant. *See, e.g.*, *Daval Steel Products, a Div. of Francosteel Corp. v. M/V Fakredine*, 951 F.2d 1357, 1368 (2d Cir. 1991); *Renner v. Chase Manhattan Bank*, No. 98 Civ. 926, 2000 WL 1848484, at *1 (S.D.N.Y. Dec. 15, 2000); *Abu-Nassar v. Elders Futures Inc.*, No. 88 Civ. 7906, 1991 WL 45062, at *17 (S.D.N.Y. Mar. 28, 1991); *United States v. Int'l Bus. Machines Corp.*, 66 F.R.D. 180, 181 (S.D.N.Y. 1974).

Speaker Program Data and Prescription Data for time periods not covered by the Amended Complaint are relevant to the Government's efforts to identify all doctors who participated in sham speaker programs during the periods that are covered by the Amended Complaint. To provide but one potential example, if a doctor received honoraria for speaking on a particular topic multiple times in 2009, but then attended that same lecture multiple times in 2010, that would tend to suggest that the 2010 events were a sham. The fact that the Government could not obtain damages for the claims that were submitted in 2009 would not mean that such pre-2010 information is irrelevant in identifying the post-release violations.

Speaker Program Data and Prescription Data for the entire time period is relevant for the additional reason that it allows the Government to conduct a comparative analysis of a doctor's prescription writing before and after such doctor began participating in Novartis speaker programs. For example, if a doctor who attended sham events during the period from 2008 through 2011 increased his or her prescription writing starting in 2008 by 30% after first receiving honoraria from Novartis and maintained that higher level of prescription writing during the entirety of the 2010 and 2011 time period, merely looking at the 2010 and 2011 Speaker Program Data and Prescription Data would not reveal that change in prescription writing behavior. Yet such information would potentially be relevant to the Government's claims for the 2010 through 2011 time period. Conversely, if a doctor participated in Novartis speaker programs from 2010 through 2013, whether the number of Novartis prescriptions written by such doctor decreased in 2014 after the doctor ceased participating in speaker events could also potentially be relevant to the Government's claims in this case.

Indeed, this Court has already found evidence of the trends and fluctuations of doctors' speaker-program attendance and prescriptions to be relevant in this case. In denying Novartis's motion to dismiss the Amended Complaint, the Court held that the Government had adequately pleaded the anti-kickback violations by alleging, among other things, that doctors' increased their prescriptions for Novartis drugs after attending speaker events: "While it is true that the doctors identified in the pleadings allegedly prescribed Novartis cardiovascular division drugs before they attended sham speaker events, the Government Entities alleged that the doctors' prescriptions for Novartis drugs significantly increased after they began attending and/or receiving honoraria for these events." (Sept. 30, 2014 Order, Dkt. 110 at 35).

To the extent that Novartis is arguing that the terms of the 2010 Release somehow prohibit the Government from using information relating to speaker program events that occurred during the Released Period to support its claims for conduct that occurred *after* the Released Period, this argument has no merit. The 2010 Release does not shield the 2002-2009 data from use in potential litigation with respect to claims arising after the Released Period. Indeed, the scope of the 2010 Release is clear: it releases *claims* the United States "has or may have *for the Covered Conduct*," which, as relevant here, is specifically limited to Novartis's "illegal remuneration" to health care professionals for prescriptions of Diovan, Exforge, and Tekturna from 2002 to 2009. (Ex. A (emphasis added)). The 2010 Release nowhere addresses Novartis's discovery obligations, or the evidentiary use that can be made of data relating to the Released Period. Thus, the September 2010 Settlement does not serve to shield information relating to the Released Period from potential discovery demands. *See Fasteners for Retail, Inc. v. Andersen*, No. 11 Civ. 2164, 2014 WL 4269055, at *4 (N.D. Ill. Aug. 22, 2014) ("[A] settlement agreement must expressly release discovery rights in order to preclude future discovery between the parties to a settlement agreement."); *Tag Grp. S.A. v. Haas & Haynie Corp.*, 637 F. Supp. 121, 124 (S.D.N.Y. 1986).

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In light of Novartis's failure to comply with its discovery obligation to produce relevant evidence, the Government intends to seek an order, pursuant to Federal Rule of Civil Procedure 37(a), compelling Novartis to produce all of the requested Speaker Program Data and Prescription Data. Thank you for your consideration of this matter.

Respectfully,

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